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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,642	12/22/2000	Thomas B. Albrecht	026.00041	4973

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EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/748,642

Applicant(s)

ALBRECHT ET AL.

Examiner

Dana Shin

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on March 5, 2007.

Currently, claims 6-7 and 14-15 are pending. Claims 1-5, 8-13, and 16-18 have previously been cancelled.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

Claims 6-7 and 14-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record as set forth in the Office action mailed on October 5, 2006 and for the reasons stated below.

Applicant's arguments filed on March 5, 2007 have been fully considered but they are not persuasive. The declaration under 37 CFR 1.132 filed on March 5, 2007 is insufficient to

Art Unit: 1635

overcome the rejection of claims 6-7 and 14-15 based upon lack of *in vivo* enablement requirement as set forth in the last Office action because of the following reasons:

The declaration signed by two inventors state that it was known in the art that E64d was cell membrane permeable and that it has been used in animal models to treat spinal cord injuries. To support their arguments, inventors cited two references published in 2001; that is, the references inventors cited are not prior art to the present application. Note that the earliest effective filing date of the instant application is December 23, 1999. As such, the method of reducing HCMV infection *in vivo* or method of treating HCMV infection *in vivo* in a subject must have been fully enabled at the time the application was originally filed in 1999 in such a way that one of ordinary skill in the art would have used the claimed invention in a subject *in vivo* without undue experimentation. Is applicant arguing that “cell permeability” (an inherent property of E64d) is sufficient to allow any person of ordinary skill in the art to use the claimed invention for *in vivo* therapeutic applications? As stated in the previous Office action mailed on October 5, 2006, the specification does not provide any guidance or working examples that would enable a person of ordinary skill in the art to use E64d in a subject *in vivo*, since the state of the art pertinent to treating HCMV viral infection or reducing HCMV viral replication via E64d was not fully enabled. Moreover, the instant disclosure does not set forth any specific guidance/direction as to how to practice the instantly claimed treatment method (i.e, method steps or protocols) or how to obtain the therapeutic effects required by the claims. For instance, one of ordinary skill in the art would not know what is embraced by the term “an amount of a compound effective” because there are no guidelines for determination of compound dosages needed to provide such therapeutic effect and there is no standard by which to measure whether

Art Unit: 1635

E64d will therapeutically operate *in vivo* as intended and claimed. As stated above, neither the state of the art of using E64d *in vivo* nor the content of the disclosure provides guidelines to practice the claimed therapeutic method without undue experimentation. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of treating a subject comprising administering an effective amount of E64d. For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development. See, for example, *Scott v. Finney*, 34 F.3d 1058, 1062, 32 USPQ2d 1115, 1118-19 (Fed. Cir. 1994).

Since the declaration has failed to set forth the facts or factual evidence supporting that the claimed invention was fully enabled at the time the application was filed in 1999, and since the facts provided by inventors (cell permeability, spinal cord injury animal model, publication date of cited references) are not germane to the rejection at issue, §112 enablement rejection is deemed appropriate, and therefore, claims 6-7 and 14-15 remain rejected under 35 U.S.C. 112, first paragraph.

New Objections/Rejections

Claim Objections

Claim 7 is objected to because of the following informalities: Line 5 recites “E64D” while claim 15 recites “E64d”. It is noted that “E64d” is an art-recognized diction/spelling. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleina et al.

(*Journal of Virology*, 1992, 66:7168-7175).

The claims embrace *in vitro* method of decreasing viral replication of HCMV in cells comprising administering E64d to cells.

Kleina et al. teach that E64d is membrane permeable (page 7168). They teach that E64d interferes with assembly and replication of foot-and-mouth disease virus (FMDV) in infected LF-BK cells *in vitro* (pages 7168-7172). Since Kleina et al. perform the active steps of the claimed method, it is anticipated that the method of Kleina et al. comprising E64d will result in a decreased viral replication of HCMV in cells *in vitro* by inherently increasing the levels of p21^{cip1}, absent evidence to the contrary.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al.

(*Virology*, 1995, 208:1-8).

The claims are described above.

Kim et al. teach that E64d is a specific, irreversible cysteine proteinase inhibitor. They teach that E64d inhibits replication of mouse hepatitis virus strain A59 (MHV-A59) in infected murine DBT cells *in vitro* (pages 1-6). Since Kim et al. perform the active steps of the claimed

Art Unit: 1635

method, it is anticipated that the method of Kim et al. will result in a decreased viral replication of HCMV in cells *in vitro* by inherently increasing the levels of p21^{cip1}, absent evidence to the contrary.

Conclusion

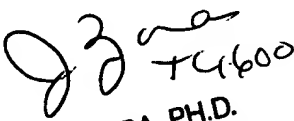
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635


JANE ZARA, PH.D.
PRIMARY EXAMINER